K021826

P. 1/2

zimmer

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

Summary of Safety and Effectiveness

Submitted By:

DEC 2 0 2002

Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708
574-267-6131

Contact Person:

Karen Cain
Manager, Regulatory Affairs
Telephone: 574-372-4219
FAX: 574-372-4605

Date:

October 1, 2002

Trade Name:

Trilogy® Acetabular System Constrained Liner

Common Name:

Constrained Acetabular Liner

Classification Name:

Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis

Predicate Devices:

- Johnson & Johnson POLY-DIAL Constrained Acetabular Liner for the S-ROM Total Hip System, P960054, approved June 19, 1997

Description:

The *Trilogy* Constrained Liner is a polyethylene liner assembly used in conjunction with a *Trilogy* Acetabular System metal shell in total hip arthroplasty procedures. The liner consists of two pieces: a liner and a constraining ring. The liner is manufactured from ultra-high molecular-weight polyethylene (UHMWPE) and the constraining ring is manufactured from *Tivanium*® Ti-6Al-4V Alloy.

The *Trilogy* Constrained Liner is offered with a 32mm internal diameter and 50-80mm outer diameter sizes. The inner diameter and face of the liner is oblique by 10 degrees resulting in offset and slight eccentricity between the internal and external diameter centers. This resultant offset acts to reduce soft tissue laxity and increase length which can contribute to joint instability. The 10-degree face can be rotated to reposition coverage opposite the direction of anticipated instability.

Intended Use/Indications for Use

The *Trilogy* Constrained Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

Comparison to Predicate Devices

The acetabular cup listed above is substantially equivalent to the *Trilogy* Constrained Liner in that both are intended to replace the bearing surface of the acetabulum in patients at high risk of dislocation. The predicate device, as well as the *Trilogy* Constrained Liner, is manufactured from UHMWPE and features a constraining ring made of titanium alloy which is assembled by the surgeon at the time of surgery. Static assembly and lever-out evaluations indicated that this device would perform as intended and similar to other legally marketed devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Ms. Karen Cain
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K021826
Trade/Device Name: *Trilogy*® Acetabular System Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: October 1, 2002
Received: October 3, 2002

Dear Ms. Cain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit K

510(k) Number (if known K021826

Device Name:

Trilogy® Acetabular System Constrained Liner

Indications for Use:

The *Trilogy* Constrained Liner is indicated for either cemented or noncemented use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

RA06201K.510

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K021826